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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,809	04/26/2002	Ronit Eisenberg	026549-000100US	1519

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

CROWDER, CHUN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,809

Applicant(s)

EISENBERG ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/22/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-70 and 72-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-70 and 72-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/09/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments, filed 11/22/2006, have been acknowledged.

Claims 1-62 and 71 have been canceled.

Claims 63,74-76 have been amended.

Claims 63-70 and 72-80 are pending and currently under consideration as they read on the elected species of Group A, without secondary complex, SEQ ID NO:1 as the first agent with first segment being SEQ ID NO:3, and condition of asthma.

2. This Office Action will be in response to applicant's arguments, filed 11/22/2006.

The rejections of record can be found in the previous Office Action, mailed 08/02/2006.

The text of those Sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

3. Applicant's IDS, filed 08/09/2006, is acknowledged and has been considered.

4. The three references attached in applicant's amendment as Exhibits have been listed on PTO-892.

5. Claims 63-70 and 72-80 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Holgate et al. (British Medical Bulletin. 1992. 48;1:40-50) in view of Adridor et al. (Science 1993. 262:1569-1572) and Lin et al. (US Patent 5,807,746) for reasons of record.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that there is no reasonable expectation that once a cargo peptide is transported into a cell by a cell-penetrating peptide (CPP) the peptide will retain its biological properties.

Applicant further argues that even though there is a reasonable expectation that any cell-penetrating peptide (CPP) would transport any cargo across a cell; it is still unpredictable whether the cargo would retain its biological function in the cell.

Furthermore, applicant asserts that Aridor et al. only teach that anti-allergy peptides have biological activity but not cell-penetrating peptide (CPP), while the instant claims are drawn to a combination of a cell-penetrating peptide (CPP) (SEQ ID NO:3) and an anti-allergy peptide (SEQ ID NO:1).

This is not found persuasive for following reasons:

In response to applicant's arguments that there is no expectation of success of combining the teachings of the reference, the examiner recognizes that obviousness requires only a reasonable expectation of success; the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success See MPEP 2143.02.

It is further noted that in considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968). See MPEP 2144.01.

Furthermore, specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY); and In re Burckel 201 USPQ 67 (CCPA). In re Burckel is cited in MPEP 716.02.

In this case, the teachings of Aridor et al. pertaining to the biological effect of the peptide KNNLKECGLY in inhibiting mast cell degranulation for targeting intracellular targets and the teachings of Lin et al. indicating success in importing biologically active molecules in to cell by linking cell-penetrating peptides (e.g. AAVALLPAVLLALLAP) to the biological molecules via linkers would have led one of ordinary skill in the art at the time the invention was made to combine the references to arrive at the claimed invention of method of inhibiting mast cell degranulation using a complex molecule comprising cell-penetrating peptide AAVALLPAVLLALLAP linked via a linker to the biological active peptide KNNLKECGLY capable of inhibiting mast cell degranulation.

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combination of references. See MPEP 2145.

Here, given the teachings of Holgate et al regarding the role of mast cell degranulation in asthma, and the teachings of Aridor et al. and Lin et al. providing the method of inhibiting mast cell degranulation by synthetic peptide KNNLKECGLY and methods of delivering biological molecule into cell using of importation competent signal peptide AAVALLPAVLLALLAP, the ordinary artisan at the time the invention was made would have had a reasonable expectation of success in producing the claimed methods.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rejections of record are maintained for the reasons of record, as they apply to the amended claims. The rejections of record are incorporated by reference herein as if reiterated in full.

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6. Claims 64 and 65 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Holgate et al. (British Medical Bulletin. 1992. 48;1:40-50) in view of Adridor et al. (Science 1993. 262:1569-1572) and Lin et al. (US Patent 5,807,746) as applied to claim 63 above, further in view of Avruch et al. (US Patent 6,103,692) and Jackson et al. (J. Am. Chem. Soc. 1994. 116:3220-3230) for reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same as above in Section 5.

The rejections of record are maintained for the reasons of record, as they apply to the amended claims. The rejections of record are incorporated by reference herein as if reiterated in full.

7. Claims 63-70 and 72-80 are provisionally rejected on the ground of **nonstatutory obviousness-type double patenting** as being unpatentable over claims 1-44 of copending USSN 10/465,826, and claims 1-15 of the copending USSN 11/214,588 for reasons of record.

Applicant argues that the rejection on the ground of provisional double patenting must be withdrawn when it is the sole remaining basis for rejection.

Given that the rejections under 35 U.S.C. 103(a) have been maintained for reasons stated above in Sections 5 and 6 and a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) has not been filed; the rejection on the basis of double patenting will be maintained until such a time that allowable subject matter is determined or a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) is timely filed.

8. Upon further consideration as well as applicant's amendment, the previous rejection under **35 U.S.C. 112, first paragraph** has been withdrawn.

9. *Conclusion: no claim is allowed.*

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
December 4, 2006

Phillip Gambel
PHILLIP GAMBEL, PH.D. JD
PRIMARY EXAMINER
TZ 1600
12/15/06